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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,492	04/15/2005	Yasumichi Hitoshi	021044-002430US	2678

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EXAMINER

UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
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1642

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08/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/531,492

Applicant(s)

HITOSHI ET AL.

Examiner

Susan Ungar

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 15 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. Claims 1-37 are pending in the application and are currently under prosecution.
2. This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1

Group 1, claims 1-in-part, 2-4, 6-8, 14-22, 37-in-part drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 35 binding partner and determining the functional/physical effect of the compound/antibody upon the binding partner polypeptide and drawn to peptide 35.

Group 2, claims 1-in-part, 2, 5-6, 9-22 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 35 binding partner and determining the functional/chemical or phenotypic effect of the compound/antibody upon the binding partner polypeptide.

Group 3, claims 1-in-part, 2-4, 6-8, 14-22, 24 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 35 binding partner and determining the functional/physical effect of the compound/antisense upon the binding partner polypeptide.

Group 4, claims 1-in-part, 2, 5-6, 9-22, 24 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 35 binding partner and determining the functional/chemical or phenotypic effect of the compound/antisense upon the binding partner polypeptide.

Group 5, claims 1-in-part, 2-4, 6-8, 14-22, 25 drawn to a method for

identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 35 binding partner and determining the functional/physical effect of the compound/small organic molecule upon the binding partner polypeptide.

Group 6, claims 1-in-part, 2, 5-6, 9-22, 25 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 35 binding partner and determining the functional/chemical or phenotypic effect of the compound/small organic compound upon the binding partner polypeptide.

Group 7, claims 1-in-part, 2-4, 6-8, 14-22, 26-27 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 35 binding partner and determining the functional/physical effect of the compound/peptide upon the binding partner polypeptide.

Group 8, claims 1-in-part, 2, 5-6, 9-22, 26-27 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 35 binding partner and determining the functional/chemical or phenotypic effect of the compound/peptide upon the binding partner polypeptide.

Group 9, claims 1-in-part, 2-4, 6-8, 14-22, 37-in-part drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 38 binding partner and determining the functional/physical effect of the compound/antibody upon the binding partner polypeptide.

Group 10, claims 1-in-part, 2, 5-6, 9-22 drawn to a method for identifying a

compound that modulates cellular proliferation comprising contacting the compound with a peptide 38 binding partner and determining the functional/chemical or phenotypic effect of the compound/antibody upon the binding partner polypeptide.

Group 11, claims 1-in-part, 2-4, 6-8, 14-22, 24 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 38 binding partner and determining the functional/physical effect of the compound/antisense upon the binding partner polypeptide.

Group 12, claims 1-in-part, 2, 5-6, 9-22, 24 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 38 binding partner and determining the functional/chemical or phenotypic effect of the compound/antisense upon the binding partner polypeptide.

Group 13, claims 1-in-part, 2-4, 6-8, 14-22, 25 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 38 binding partner and determining the functional/physical effect of the compound/small organic molecule upon the binding partner polypeptide.

Group 14, claims 1-in-part, 2, 5-6, 9-22, 25 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 38 binding partner and determining the functional/chemical or phenotypic effect of the compound/small organic compound upon the binding partner polypeptide.

Group 15, claims 1-in-part, 2-4, 6-8, 14-22, 26-27 drawn to a method for

identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 38 binding partner and determining the functional/physical effect of the compound/peptide upon the binding partner polypeptide.

Group 16, claims 1-in-part, 2, 5-6, 9-22, 26-27 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 38 binding partner and determining the functional/chemical or phenotypic effect of the compound/peptide upon the binding partner polypeptide.

Group 17, claims 1-in-part, 2-4, 6-8, 14-22, 37-in-part drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 40 binding partner and determining the functional/physical effect of the compound/antibody upon the binding partner polypeptide.

Group 18, claims 1-in-part, 2, 5-6, 9-22 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 40 binding partner and determining the functional/chemical or phenotypic effect of the compound/antibody upon the binding partner polypeptide.

Group 19, claims 1-in-part, 2-4, 6-8, 14-22, 24 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 40 binding partner and determining the functional/physical effect of the compound/antisense upon the binding partner polypeptide.

Group 20, claims 1-in-part, 2, 5-6, 9-22, 24 drawn to a method for

identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 40 binding partner and determining the functional/chemical or phenotypic effect of the compound/antisense upon the binding partner polypeptide.

Group 21, claims 1-in-part, 2-4, 6-8, 14-22, 25 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 40 binding partner and determining the functional/physical effect of the compound/small organic molecule upon the binding partner polypeptide.

Group 22, claims 1-in-part, 2, 5-6, 9-22, 25 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 40 binding partner and determining the functional/chemical or phenotypic effect of the compound/small organic compound upon the binding partner polypeptide.

Group 23, claims 1-in-part, 2-4, 6-8, 14-22, 26-27 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 40 binding partner and determining the functional/physical effect of the compound/peptide upon the binding partner polypeptide.

Group 24, claims 1-in-part, 2, 5-6, 9-22, 26-27 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 40 binding partner and determining the functional/chemical or phenotypic effect of the compound/peptide upon the binding partner polypeptide.

Group 25, claims 1-in-part, 2-4, 6-8, 14-22, 37-in-part drawn to a method for

identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 41 binding partner and determining the functional/physical effect of the compound/antibody upon the binding partner polypeptide.

Group 26, claims 1-in-part, 2, 5-6, 9-22 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 41 binding partner and determining the functional/chemical or phenotypic effect of the compound/antibody upon the binding partner polypeptide.

Group 27, claims 1-in-part, 2-4, 6-8, 14-22, 24 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 41 binding partner and determining the functional/physical effect of the compound/antisense upon the binding partner polypeptide.

Group 28, claims 1-in-part, 2, 5-6, 9-22, 24 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 41 binding partner and determining the functional/chemical or phenotypic effect of the compound/antisense upon the binding partner polypeptide.

Group 29, claims 1-in-part, 2-4, 6-8, 14-22, 25 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 41 binding partner and determining the functional/physical effect of the compound/small organic molecule upon the binding partner polypeptide.

Group 30, claims 1-in-part, 2, 5-6, 9-22, 25 drawn to a method for

identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 41 binding partner and determining the functional/chemical or phenotypic effect of the compound/small organic compound upon the binding partner polypeptide.

Group 31, claims 1-in-part, 2-4, 6-8, 14-22, 26-27 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 41 binding partner and determining the functional/physical effect of the compound/peptide upon the binding partner polypeptide.

Group 32, claims 1-in-part, 2, 5-6, 9-22, 26-27 drawn to a method for identifying a compound that modulates cellular proliferation comprising contacting the compound with a peptide 41 binding partner and determining the functional/chemical or phenotypic effect of the compound/peptide upon the binding partner polypeptide.

Group 33, claims 28-in-part, 29-31 drawn to a method of modulating cellular proliferation in a subject comprising administering a therapeutically effective amount of a compound that has a functional effect on peptide 35, wherein the compound is an antibody.

Group 34, claims 28-in-part, 29-30, 32 drawn to a method of modulating cellular proliferation in a subject comprising administering a therapeutically effective amount of a compound that has a functional effect on peptide 35, wherein the compound is an antisense.

Group 35, claims 28-in-part, 29-30, 33 drawn to a method of modulating cellular proliferation in a subject comprising administering a therapeutically effective amount of a compound that has a functional effect on peptide 35, wherein

the compound is a small organic molecule.

Group 36, claims 28-in-part, 29-30, 35-36 drawn to a method of modulating cellular proliferation in a subject comprising administering a therapeutically effective amount of a compound that has a functional effect on peptide 35, wherein the compound is a peptide.

Group 37, claims 28-in-part, 29-31 drawn to a method of modulating cellular proliferation in a subject comprising administering a therapeutically effective amount of a compound that has a functional effect on peptide 38, wherein the compound is an antibody.

Group 38, claims 28-in-part, 29-30, 32 drawn to a method of modulating cellular proliferation in a subject comprising administering a therapeutically effective amount of a compound that has a functional effect on peptide 38, wherein the compound is an antisense.

Group 39, claims 28-in-part, 29-30, 33 drawn to a method of modulating cellular proliferation in a subject comprising administering a therapeutically effective amount of a compound that has a functional effect on peptide 38, wherein the compound is a small organic molecule.

Group 40, claims 28-in-part, 29-30, 35-36 drawn to a method of modulating cellular proliferation in a subject comprising administering a therapeutically effective amount of a compound that has a functional effect on peptide 38, wherein the compound is a peptide.

Group 41, claims 28-in-part, 29-31 drawn to a method of modulating cellular proliferation in a subject comprising administering a therapeutically effective amount of a compound that has a functional effect on peptide 40, wherein the compound is an antibody.

Group 42, claims 28-in-part, 29-30, 32 drawn to a method of modulating cellular proliferation in a subject comprising administering a therapeutically effective amount of a compound that has a functional effect on peptide 40, wherein the compound is an antisense.

Group 43, claims 28-in-part, 29-30, 33 drawn to a method of modulating cellular proliferation in a subject comprising administering a therapeutically effective amount of a compound that has a functional effect on peptide 40, wherein the compound is a small organic molecule.

Group 44, claims 28-in-part, 29-30, 35-36 drawn to a method of modulating cellular proliferation in a subject comprising administering a therapeutically effective amount of a compound that has a functional effect on peptide 40, wherein the compound is a peptide.

Group 45, claims 28-in-part, 29-31 drawn to a method of modulating cellular proliferation in a subject comprising administering a therapeutically effective amount of a compound that has a functional effect on peptide 41, wherein the compound is an antibody.

Group 46, claims 28-in-part, 29-30, 32 drawn to a method of modulating cellular proliferation in a subject comprising administering a therapeutically effective amount of a compound that has a functional effect on peptide 41, wherein the compound is an antisense.

Group 47, claims 28-in-part, 29-30, 33 drawn to a method of modulating cellular proliferation in a subject comprising administering a therapeutically effective amount of a compound that has a functional effect on peptide 41, wherein the compound is a small organic molecule.

Group 48, claims 28-in-part, 29-30, 35-36 drawn to a method of modulating

cellular proliferation in a subject comprising administering a therapeutically effective amount of a compound that has a functional effect on peptide 41, wherein the compound is a peptide.

Group 49, claim 37-in-part, drawn to a peptide comprising peptide 38.

Group 50, claim 37-in-part, drawn to a peptide comprising peptide 40.

Group 51, claim 37-in-part, drawn to a peptide comprising peptide 41.

3. The inventions are distinct, each from the other because of the following reasons:

A national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

Group 1, claims 1-in-part, 2-4, 6-8, 14-22, 37-in-part form a single general inventive concept.

Groups 2-48 are methods additional.

Groups 49-51 are drawn to peptides not used in the methods of Group 1.

Because these inventions are distinct for the reasons given above restriction for examination purposes as indicated is proper.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

6. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

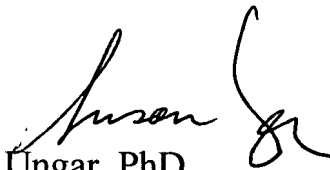
In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See “Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b),” 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against

double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (571) 272-0837. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached at 571-272-0898. The fax phone number for this Art Unit is (571) 273-8300.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.


Susan Ungar, PhD
Primary Patent Examiner
August 10, 2007